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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,509	05/21/2002	Eric Paul Krenning	0702-020040	6829
28289	7590	11/08/2005	EXAMINER	
THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,509

Applicant(s)

KRENNING ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53,55-58 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53,55-58 and 60-63 is/are rejected:
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed August 29, 2005 have been entered.

No claim was amended. Claims 53, 55-58, and 60-63 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53, 55-58, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,648,059 ('059), US 5,843,894 ('894) and Hammond et al. (Br. J. Cancer, 1993;67:1437-1439) from IDS filed April 21, 2003).

'059 teaches L-lysine, arginine and ornithine as useful as inhibiting the retention and reabsorption of therapeutic immunoconjugate such as antibodies and monoclonal antibodies (See claims 1, 2, 3, and 5). '059 teaches protein uptake by the kidney as decreased when a dosage of 10mg lysine is administered to a rat animal (See col. 10-11, Examples I-III).

'894 teaches D-Lysine as useful in a method of reducing the uptake of antibody fragments (See the abstract). '894 teaches the effective dosage of lysine and pollysine solution effective in reducing uptake of antibody fragments as 2-35g/L and 10-25g/L respectively (See col. 6, lines 15-28).

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Hammond teaches amino acids 4.93g/L of lysine and 17.6 g /L of arginine as useful in blocking renal tubular uptake of somatostatin (See page 1437, col.2, Materials and Methods section).

The references do not expressly teach the herein claimed dosage of lysine and arginine. The references do not expressly teach the use of lysine and arginine together.

It would have been obvious to one of ordinary skill in the art at the time the invention made to adjust amount of the herein claimed active to the herein claimed dosage. It would have been obvious to one of ordinary skill in the art at the time of invention to employ lysine and arginine together in a method of inhibiting renal reuptake of protein or peptides.

One of ordinary skill in the art would have been motivated to adjust amount of lysine, polylysine, and arginine to the herein claimed dosage since the optimization of the result parameters as within the purview of the skilled artisan, absent evidence to the contrary. One of ordinary skill in the art would have been motivated to employ lysine and arginine together in a method of inhibiting renal reuptake of protein since they are known to be useful individually to inhibit or reducing the renal uptake of antibodies or fragments, concomitantly employing both agents for the very same purpose would be prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). At least additive effect would be expected.

Response to Arguments

Applicant's arguments filed August 29, 2005 averring 059 and '894's failure to teach the combination of herein claimed amino acids have been fully considered but

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they are not persuasive. The new ground of rejection is presented in the instant office action and therefore, such arguments are considered moot.


Applicant's arguments filed August 29, 2005 averring Hammond's failure to teach the combination of only two amino acids have been fully considered but they are not persuasive. Examiner notes that the method recited herein contains the phrase "comprising" which is an open-end transitional phrase that permit anything other than lysine and arginine be employed in the instant method. Therefore, the claims are still considered properly rejected under 35 USC 103(a)/

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


San-ming Hui
Primary Examiner
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